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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,960	10/19/2001	Maria A. Glucksmann	MPI00-437P1RM	1608

7590 09/22/2004

INTELLECTUAL PROPERTY GROUP
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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,960	GLUCKSMANN ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. ***Election***

Applicant's election of **Group I,** claims 1-3 and 6, drawn to nucleic acid sequence of SEQ ID NO: 1(cDNA) and SEQ ID NO: 3 (coding), host cell and method of making polypeptide of SEQ ID NO: 2, designated 80090, filed 26 July 2004, without prejudice is acknowledged. Applicants further state that they reserve the right to traverse the above restriction with respect to non-elected inventions of Groups 2-40 in this or subsequent applications.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP §818.03(a)).

2. Applicants have canceled all pending claims 1-24, and have added new claims 25-42, which are drawn to the subject matter of elected Group I.

3. **Claims 25-42** [SEQ ID NO: 1 or 3 encoding SEQ ID NO : 2] are under consideration in this Office Action.

4. ***Priority***

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional applications 60/242,040, filed 10.20.2000; 60/242,038 filed 10.20.2000; 60/241,992, filed 10.20.2000; and 60/242,637, filed 10.23.2000.

5. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

6. ***hyperlink***

The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (for example, pages 9 & 15 of Applicants' amendment filed July 26, 2004, is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

Applicant's cooperation is requested in correcting all ***hyperlink(s)*** which may have been added or were present in the original specification at the time of filing.

7. ***Enablement Rejection***

Claims 25, 28, 31, 34-35 & 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide sequence of SEQ ID NO: 1 or 3, encoding a fucosyltransferase of SEQ ID NO: 2, does not reasonably provide enablement for any polynucleotide having 95% identity to SEQ ID NO: 1 or 3 or that encoding a protein which is 95% identical to SEQ ID NO: 2. The specification does not enable any person skilled in the art

to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims does not commensurate with the enablement provided by the disclosure with regard to the large number of polynucleotides (or nucleic acid) broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide [SEQ ID NO: 1 (cDNA) or SEQ ID NO: 3 (coding)] and the encoded amino acid sequence of SEQ ID NO: 2.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given

protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications of DNA of SEQ ID NO: 1-3 by 5%, because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting fucosyltransferase activity; (B) the general tolerance of fucosyltransferase of SEQ ID NO: 2 to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any fucosyltransferase residues with an expectation of obtaining the desired enzymatic or biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

This is further supported in the work of Seffernick et al. [J. Bacteriol. Apr. 2001, p. 2405-2410] where melamine Deaminase and Atrazine chlorohydrolase each consists of 475 amino acids, are 98% identical and are yet functionally different. Thus there is high unpredictability associated with respect to modification(s) of the sequence of SEQ ID Nos: 1-3 unless guidance is provided in establishing (A) – (D) as discussed above. Further, the instant specification does not describe a specific assay for fucosyltransferase. It is not clear what type of fucosyltransferase is SEQ ID NO: 2. Is it alpha 1, 3-fucosyltransferase or 1, 4- fucosyltransferase, GDP-L-fucose: .beta.-D-galactoside 2-.alpha.-L fucosyltransferase or GDP-L-fucose: .beta.-D-N-

acetylglucosamide 3/4-.alpha.-L-fucosyltransferase, etc., and what the specific substrate the enzyme of SEQ ID NO: 2 uses. US 20020102604A1 disclose a human nucleic acid sequence [SEQ ID NO: 43], which is 99% identical to Applicants SEQ ID NO: 3, and encodes a secretary protein, not a fucosyltransferase.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of exact nature of fucosyltransferase encoding DNA (or polynucleotide) having the desired biological characteristics, as well as vector or host cell constructs is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

8. Claims 26-27, 29-30, 32-33, 36-39, 41-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-27, line 4, recite the phrase "amino acid sequence of SEQ ID NO: 2 or a full compliment thereof". The claims are indefinite because there is

no complimentary sequence to an amino acid sequence. Deleting a part of the phrase, i.e., "or a full compliment thereof", will overcome this rejection.

Claims 29-30, 32-33, 36-39, 41-42 are included in this rejection for failing to correct the defect present in the base claim.

9. Claims 28-30, 34-39, 41-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-30, recite "The nucleic acid molecule of claim..., further comprising vector nucleic acid sequences". The claims are indefinite because it is not clear what vector nucleic acid sequences are comprised by the nucleic acid molecule.

Perhaps Applicants want to claim " A vector comprising the nucleic acid of claim 25.." and so on, and such a language will overcome this rejection.

Claims 34-39, 41-42 are included in this rejection for failing to correct the defect present in the base claim.

10. Each of claims 31-33, have typographical errors of the same kind. For example, amending claim 31 to read, 'The nucleic acid of claim 25, further comprising a nucleic acid sequence encoding a heterologous polypeptide', is suggested to correct the typographical error. Similar corrections are suggested for claims 32 & 33.

11. Claims 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a

gap between the steps. See MPEP § 2172.01. The omitted step(s) is/are: for example.....is expressed into the culture medium and is collected [or describe how the expressed protein is obtained].

12. Claims 25-42 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicants disclose a nucleic acid sequence (SEQ ID NO: 1 or 3) encoding the amino acid sequence of SEQ ID NO: 2. Based on reasonable sequence homology, the polypeptide of SEQ ID NO: 2 is sought to be a polypeptide having fucosyltransferase activity which is a generic asserted utility. Polypeptide(s) fucosyltransferase activity belong to no known family of enzymes or proteins involve in any specific biological process(es). It is nearly impossible from sequence homology alone to attribute a specific and substantial function for the protein. This is specially so in view of different fucosyltransferases having different substrate requirements for carrying out the enzyme assays and no specific assay is disclosed. Even accepting the plausible utility of being a polypeptide having fucosyltransferase activity, one of ordinary skill in the art would not know which one of several fucosyltransferases are associated with the polypeptide. The specification does not disclose a specific function of the polypeptides of SEQ ID NO: 2, its relationship to any disease, or any specific real world use. It appears that the main utility of the polypeptide and nucleic acid is to carry out further research to identify the biological function and

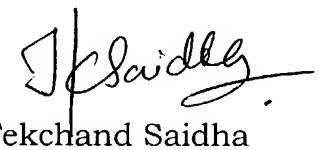
possible diseases associated with said function. Substantial utility defines a real world use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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